

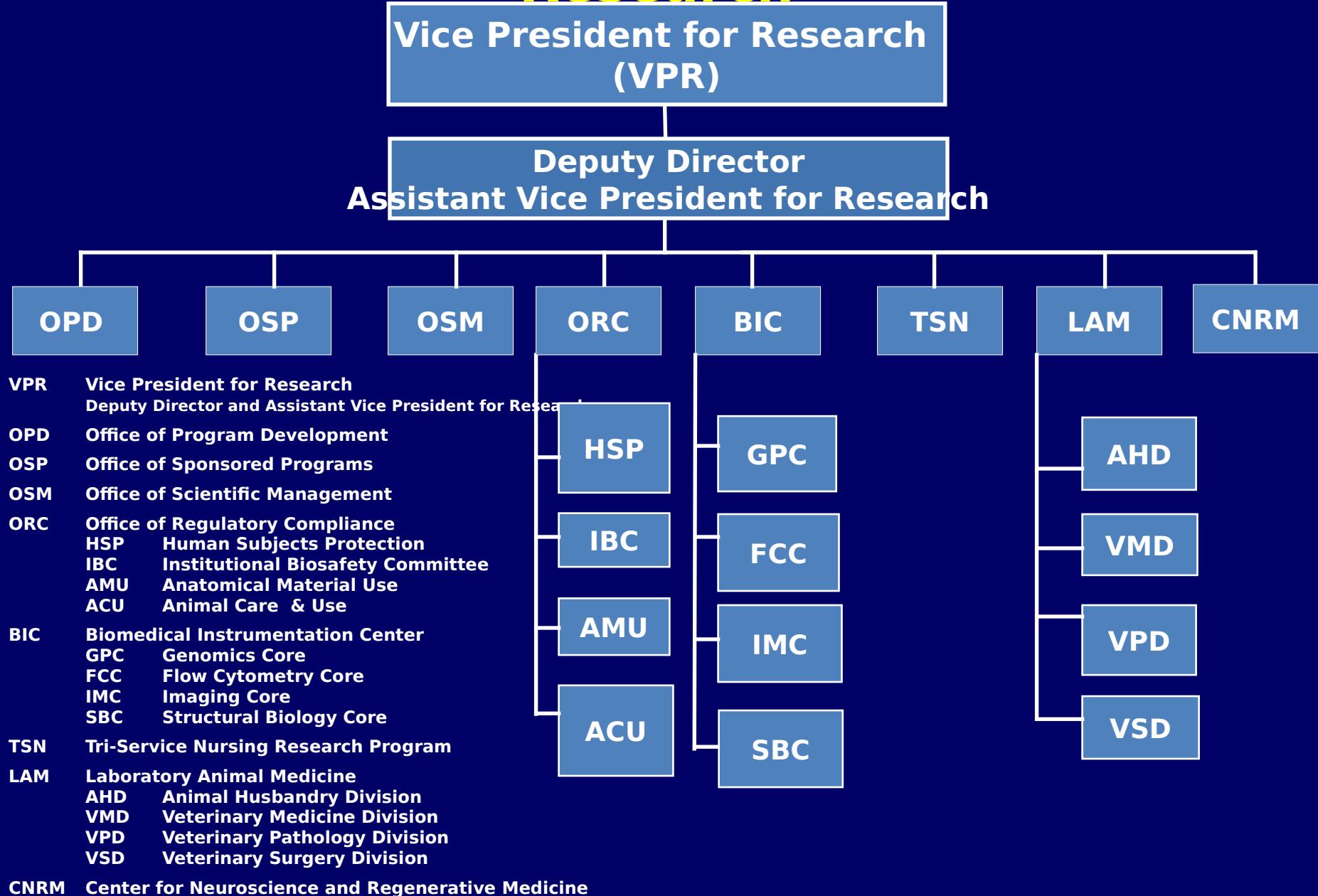
Office of Research

Uniformed Services University of the Health Sciences

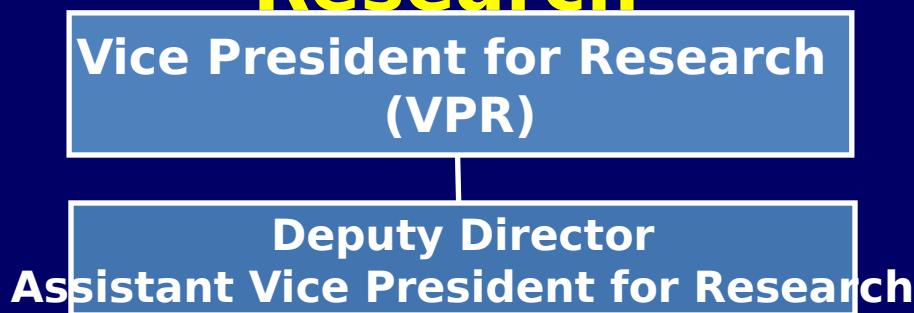
**Steven G. Kaminsky, Ph.D.
Vice President for Research**

13 October 2011

Organizational Chart for Vice President for Research



Organizational Chart for Vice President for Research



| | |
|------|--|
| VPR | Vice President for Research Deputy Director and Assistant Vice President for Research |
| OPD | Office of Program Development |
| OSP | Office of Sponsored Programs |
| OSM | Office of Scientific Management |
| ORC | Office of Regulatory Compliance |
| | HSP Human Subjects Protection |
| | IBC Institutional Biosafety Committee |
| | AMU Anatomical Material Use |
| | ACU Animal Care & Use |
| BIC | Biomedical Instrumentation Center |
| | GPC Genomics Core |
| | FCC Flow Cytometry Core |
| | IMC Imaging Core |
| | SBC Structural Biology Core |
| TSN | Tri-Service Nursing Research Program |
| LAM | Laboratory Animal Medicine |
| | AHD Animal Husbandry Division |
| | VMD Veterinary Medicine Division |
| | VPD Veterinary Pathology Division |
| | VSD Veterinary Surgery Division |
| CNRM | Center for Neuroscience and Regenerative Medicine |

Office of Program Development (OPD)

Susan B. Rasmussen, Ph.D.
Director

srasmussen@usuhs.mil
301-295-3303

Office of Program Development: Roles of the Intramural Research Program

- Enables USU faculty to begin research directed at maintaining a fit and healthy force
- Enables USU to recruit and retain high quality clinician-investigators and biomedical scientists
- Enhances USU faculty's ability to compete for extramural research funds
- Supports training of the next generation of government medical research scientists and physicians with sound understanding of the scientific basis of good medicine
- Supports continued academic accreditation for the University's programs in higher education

Office of Program Development: Intramural Research Program

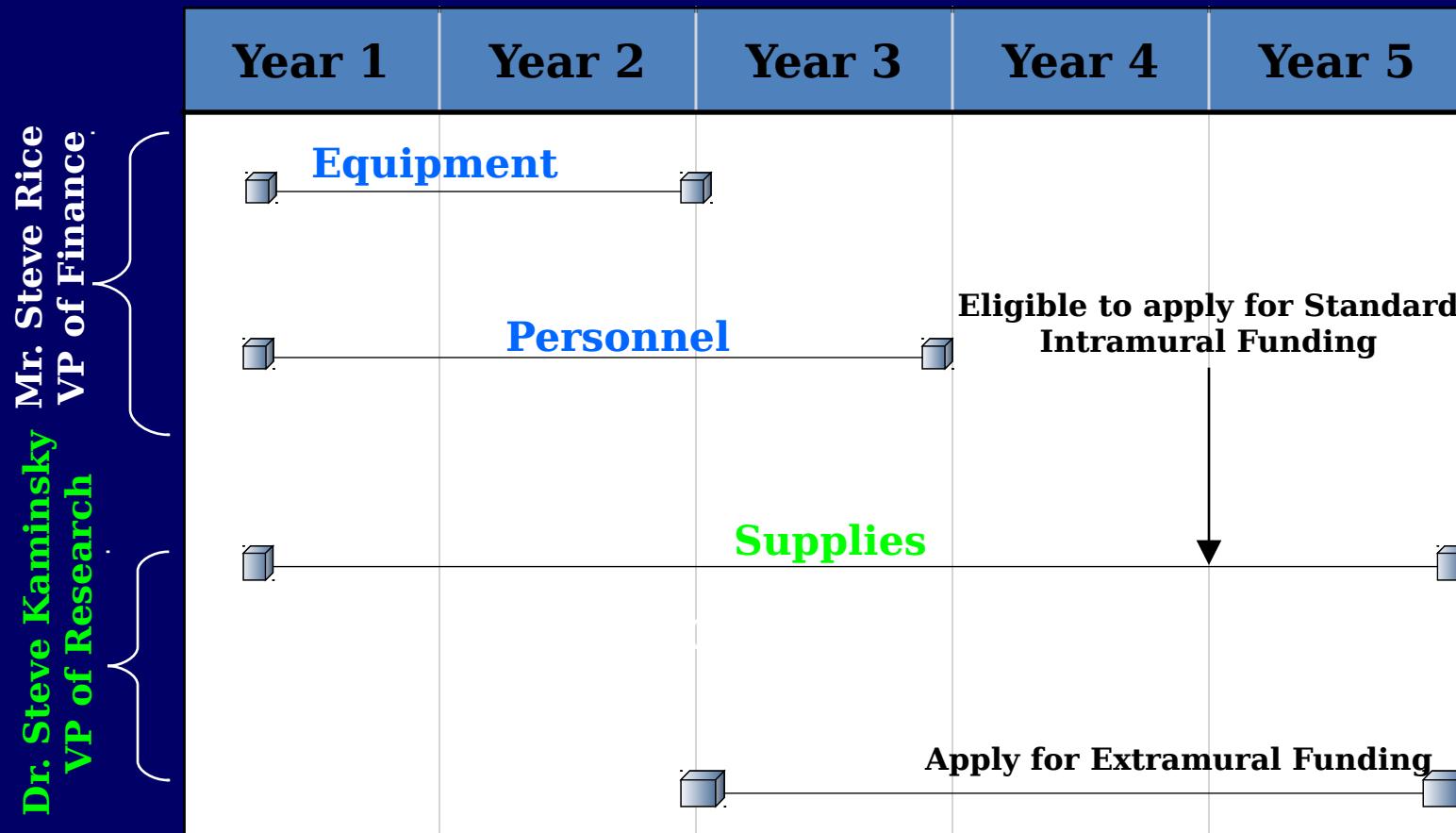
| Award Type | Funding Ceiling | Project Period |
|-------------------|------------------------|-----------------------|
| Exploratory | \$75,000 per year | Up to 24 months |
| Standards | \$20,000 per year | Up to 36 months |
| Pilots | \$10,000 per year | Up to 24 months |
| Instructional | \$10,000 per year | Up to 24 months |
| Clinical Fellows | \$3,000 per year | Up to 24 months |
| Graduate Students | \$2,500 per year | Up to 24 months |
| Medical Students | \$1,000 per year | Up to 12 months |
| | | |
| Startup Equipment | Negotiated at hiring | 24 months |
| Startup Personnel | Negotiated at hiring | 36 months |
| Startup Supplies | Negotiated at hiring | Up to 60 months |

USU Intramural Program

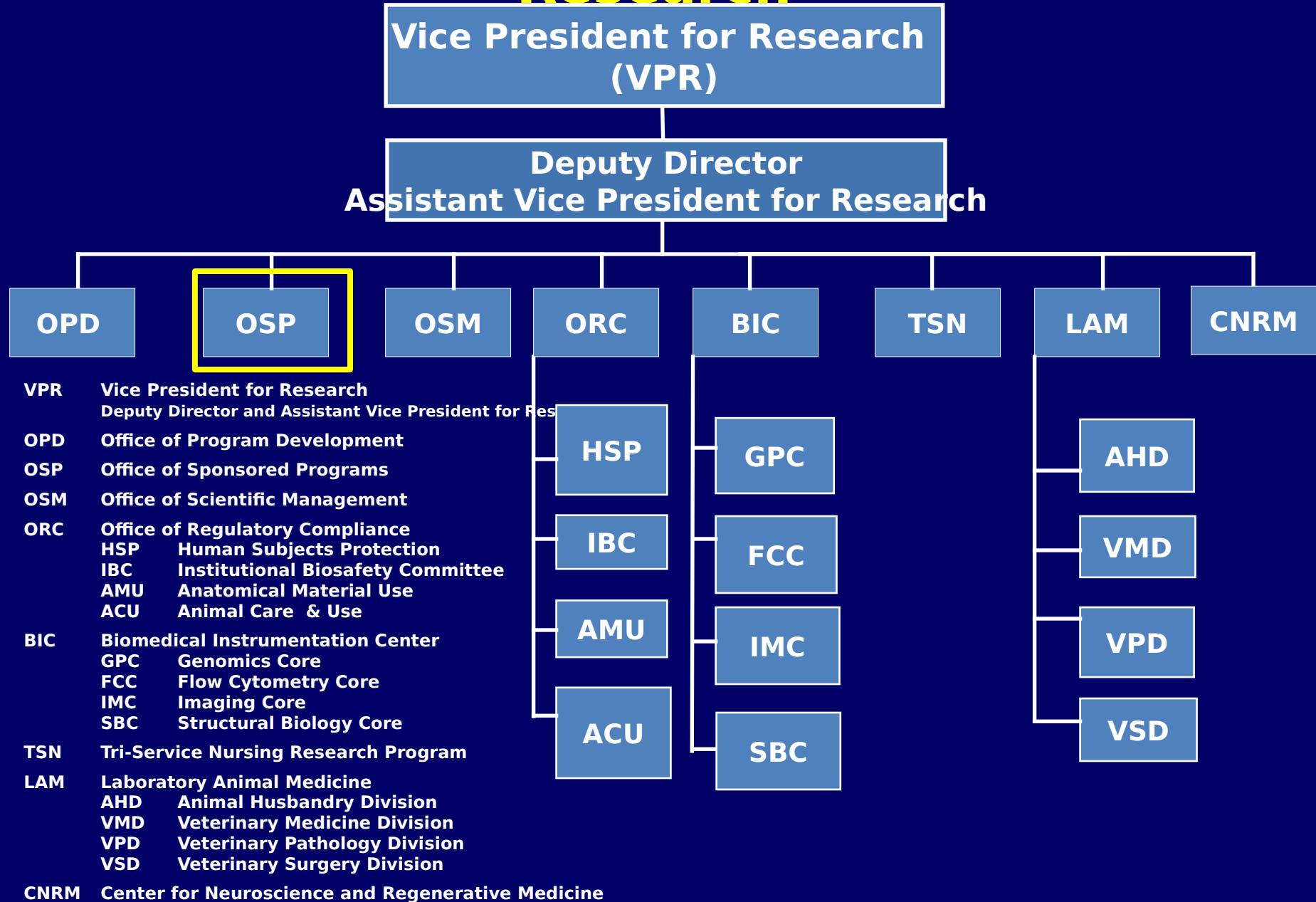
“Evolution of Funding”



Start Up Funding



Organizational Chart for Vice President for Research



Office of Sponsored Programs (OSP)

Toya V. Randolph, Ph.D.,
MSPH

Director

tr Randolph@usuhs.mil
301-295-3303

USU OSP - Overview & Mission

- Oversees administrative activities related to the **pre- and post-award** management of **extramural** research projects for USU faculty & AFRRI scientists
- Strives to provide friendly, efficient, courteous, & knowledgeable service
- Team of Grants Management Specialists to assist with extramural application submissions
- Each department has an assigned Specialist
- Works with the Henry M. Jackson Foundation for a smooth and efficient transition of USU applications & awards
- Open door policy

Henry M. Jackson Foundation

- Created in 1983 as a non-profit corporation
- Chartered by Congress to “promote the welfare of the Uniformed Services University...”
 - Supports many USU research projects
 - Over 400 employees at USU, more than 80 with Visas
 - Including Sponsored Project Administrators (SPA) for every academic department at USU
- Technology Transfer
- Located 6 miles north of USU on Rockledge Drive

HJF Contacts

Betsy Folk

VP Office of Sponsored Projects

osp@hjf.org

240-694-2020

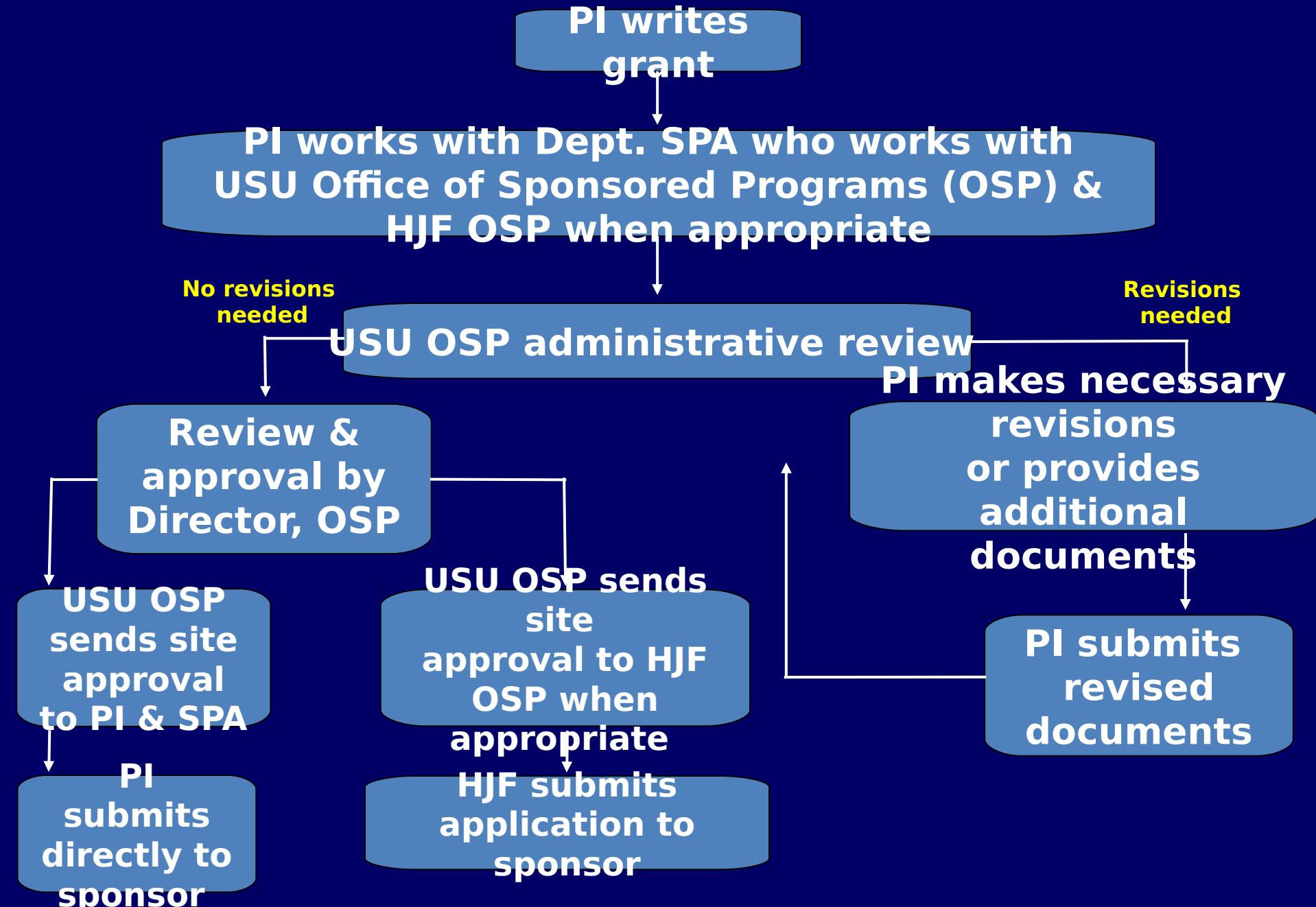
Alyssa Shepard, Ph.D.

Director, USU Services

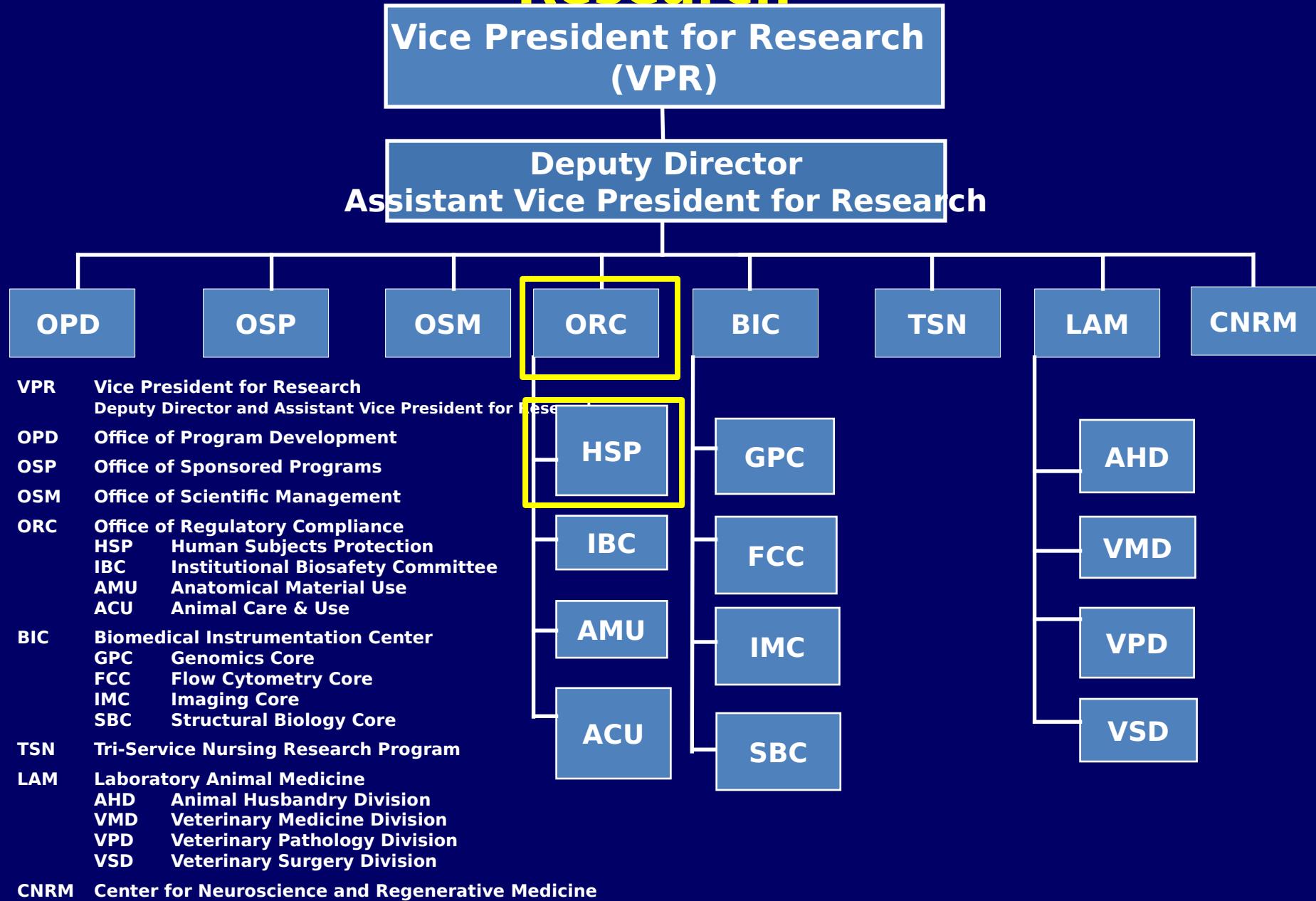
ashepard@usuhs.mil or USUServices@hjf.org

240-694-2087

Extramural Funding Submission Process



Organizational Chart for Vice President for Research



Institutional Review Board (IRB)

Ms. Maggie Pickerel, CIP

Director, Human Research Protections Program

mpickerel@usuhs.mil

IRB Office (A2051)

301-295-9534

IRB

Chair: IRB #1

Edmund (Randy) Howe,
M.D., J.D.

ehowe@usuhs.mil
301-295-3097

Chair: ID IRB

CAPT Trueman Sharp, MC,
USN

tsharp@usuhs.mil
301-295-3637

IRB #1 Administrator

Micah Stretch, J.D.
mstretch@usuhs.mil
301-295-0819

ID IRB Administrator

Vicki Zajack, MPH, CIP
Victoria.zajack.ctr@usuhs.
mil
301-319-0444

IRB: Roles and Functions

- Protects the rights and welfare of human research subjects
- Reviews research protocols to assess risks and benefits to subjects in research
- Ensures risks are minimized and reasonable in relationship to anticipated benefits
- Ensures voluntary participation of research, equitable selection, and informed consent
- Ensures compliance with DoD and federal regulations
- Recommends approval, disapproval, modification, tabling of protocols

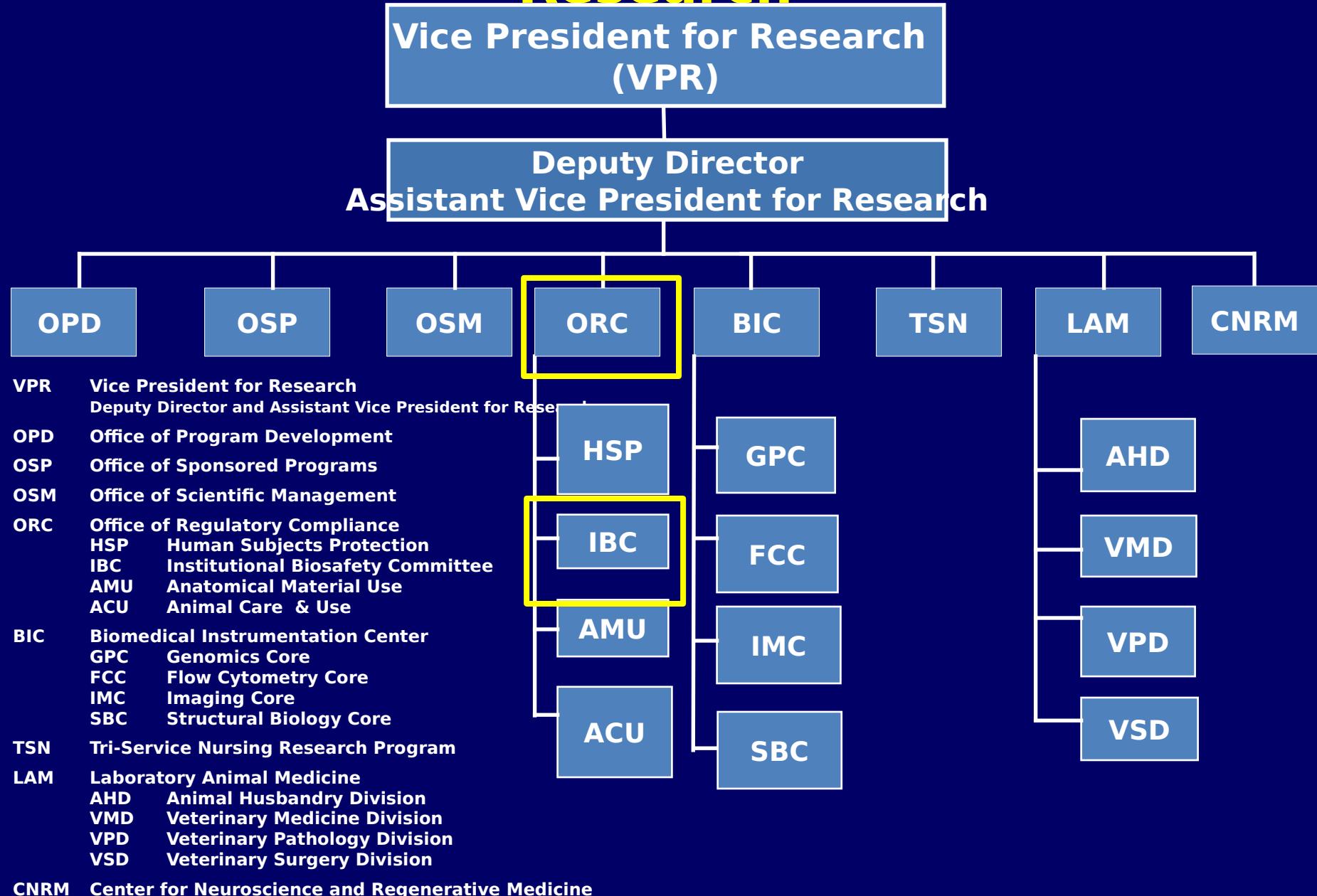
IRB: PI's Role

- Submit protocol and related paperwork via IRBNet
- Use only the latest forms (located on IRBNet) -- no other forms permissible
- Ensure paperwork is complete -- Only complete paperwork will be reviewed
- List only one PI on the protocol (others are AIs/collaborators)
- Ensure congruence between funded grant and protocol
- Be aware of DoD 'unique' regulations: e.g., no waiver of informed consent for experimental subjects; intent to benefit for subjects unable to provide consent; research monitor for more than minimal risk research; special permission for USU uniformed students as subjects, etc.
- Meet with IRB staff early for guidance, especially for multisite and protocols conducted offsite

IRB Facts

- USU has 2 IRBs: IRB #1 and the (central) Infectious Disease IRB
- Scheduled meetings: 2nd or 3rd Thursday
- Types of Protocol Review: Exempt, Expedited, Full Board, Non-human Subjects Research (NHSR)
- Exemption/NHSR determination made **only** by USU Exemption Determination Official (EDO)
- IRB = Privacy Board for HIPAA & Privacy Act issues
- Review/approval times depend upon protocol complexity, scheduling, workload, etc.
- Initial and continuing training required of all key research team members (initial: www.citiprogram.org)
- Secondary IRB review process required for research performed offsite (e.g., WRNMMC)
- [*http://www.usuhs.mil/research/RegPolicies.html*](http://www.usuhs.mil/research/RegPolicies.html)

Organizational Chart for Vice President for Research



Institutional Biosafety Committee (IBC)

Chair

Dr. Gabriela Dveksler
Dept of Pathology
gdveksler@usuhs.mil
301-295-3332

Peter Bouma
Biosafety Officer
pbouma@usuhs.mil
301-295-9443

Ms. Melanie Hazzard
Regulatory Affairs
Coordinator

Melanie.hazzard@usuhs.mi
l
301-295-9509

Institutional Biosafety Committee (IBC)

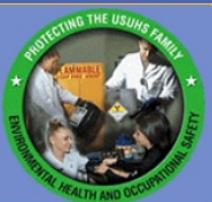
- Ensures compliance with *NIH Guidelines*
- Reviews protocols with rDNA & pathogens
- Appendix 4 of USUHS 3208 - Assurance Supplement

EHS Webpage

 **UNIFORMED SERVICES UNIVERSITY**
of the Health Sciences

SEARCH USU

VISITORS ADMISSIONS STUDENTS ALUMNI FACULTY STAFF MILITARY RESEARCH AFFILIATIONS myUSU



Environmental Health & Occupational Safety

[EHS Main](#)
[Divisions](#)
[Industrial Hygiene & Environment](#)
[Radiation Safety](#)
[Occupational Medicine](#)
[Pharmacy](#)
[Safety and Occupational Health](#)
[About EHS](#)
[Laboratory Safety](#)
[Services](#)
[Forms](#)
[Fact Sheets](#)
[Inspections](#)
[USU Instructions](#)
[Inventories](#)
[Links](#)
[Report a Hazard/Safety Concern](#)
[Report an Injury](#)
[Training](#)
[Waste](#)

Protecting the USU Family

Points of Contact are listed on each Division page

→ [CHEM/BIO WEB ACCESS](#)
→ [RAD WEB ACCESS](#)
→ [LABORATORY DECOMMISSIONING GUIDE](#)

Bulletins

Policy Statements, Guidance, Rights and Responsibilities

[COMMITMENT TO HEALTH AND SAFETY](#)
[SAFE AND HEALTHFUL WORKPLACE \(OSHA Bulletin\)](#)
[DOD SAFETY AND OCCUPATIONAL HEALTH PROTECTION PROGRAM](#)
[RADIATION SAFETY PROGRAM ENFORCEMENT POLICY](#)

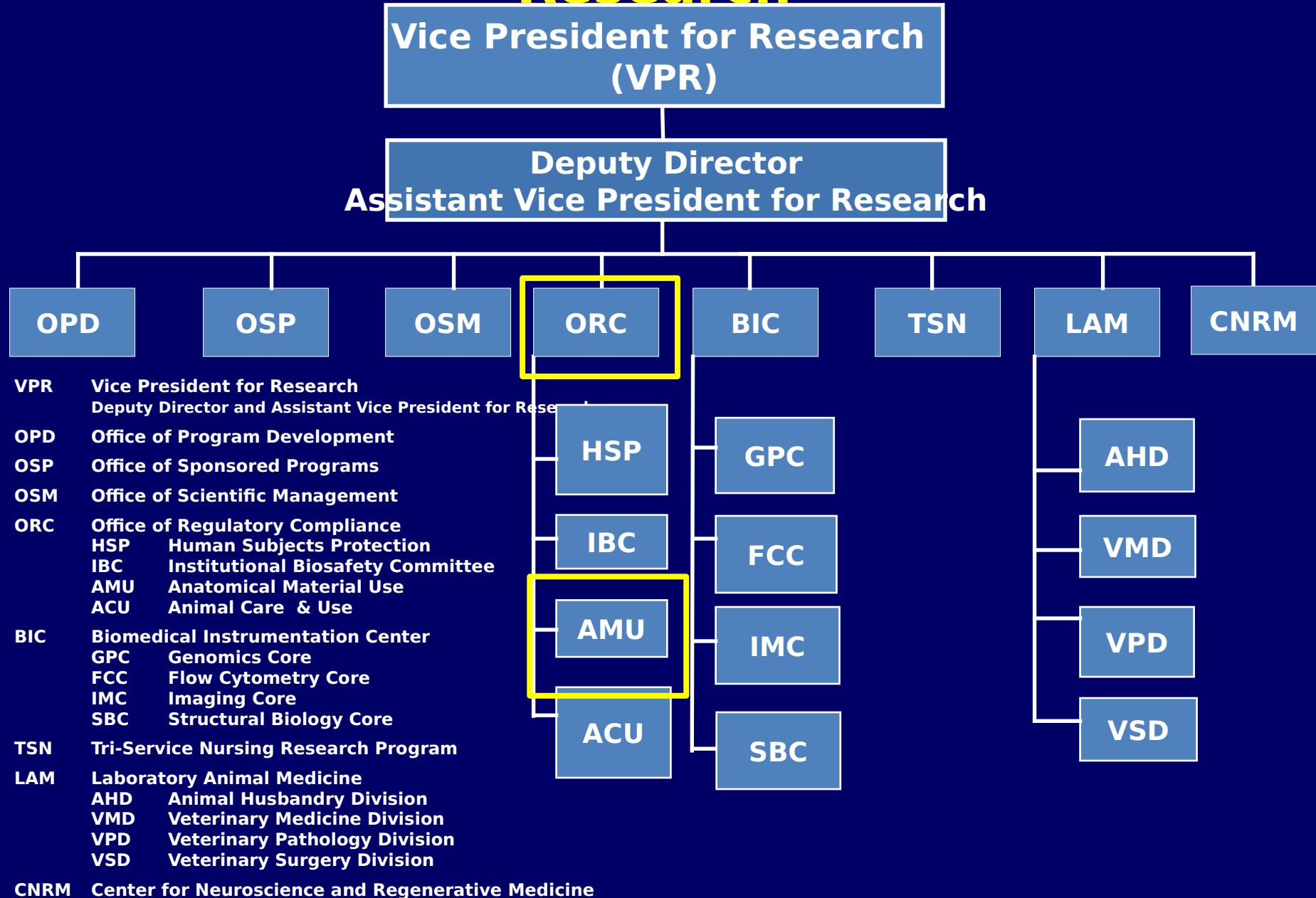
Our Mission:

To provide for a safe and healthful work environment for all students, faculty and staff in the day to day operations of the Uniformed Services University of the Health Sciences. To protect the University environment, in which we work and live through responsible stewardship and use of the tools, materials and environmental resources entrusted to our care.

You can find the following:

- **Lab Safety Information & Guidance**
- **Training Presentations**
- **Access to EHS Assistant**
 - **Training records**
 - **Chem & Bio Inventory**
 - **Radiation records**
- **Report an Injury**
- **Forms & USUHS Instructions**
- **Waste management**
- **Contact Information**

Organizational Chart for Vice President for Research



Anatomical Material Review Committee (AMRC)

Chair

Alan Seyfer, M.D.

Department of Anatomy, Physiology and Genetics

aseyfer@usuhs.mil

301-295-0441

Ms. Melanie Hazzard

Regulatory Affairs Coordinator

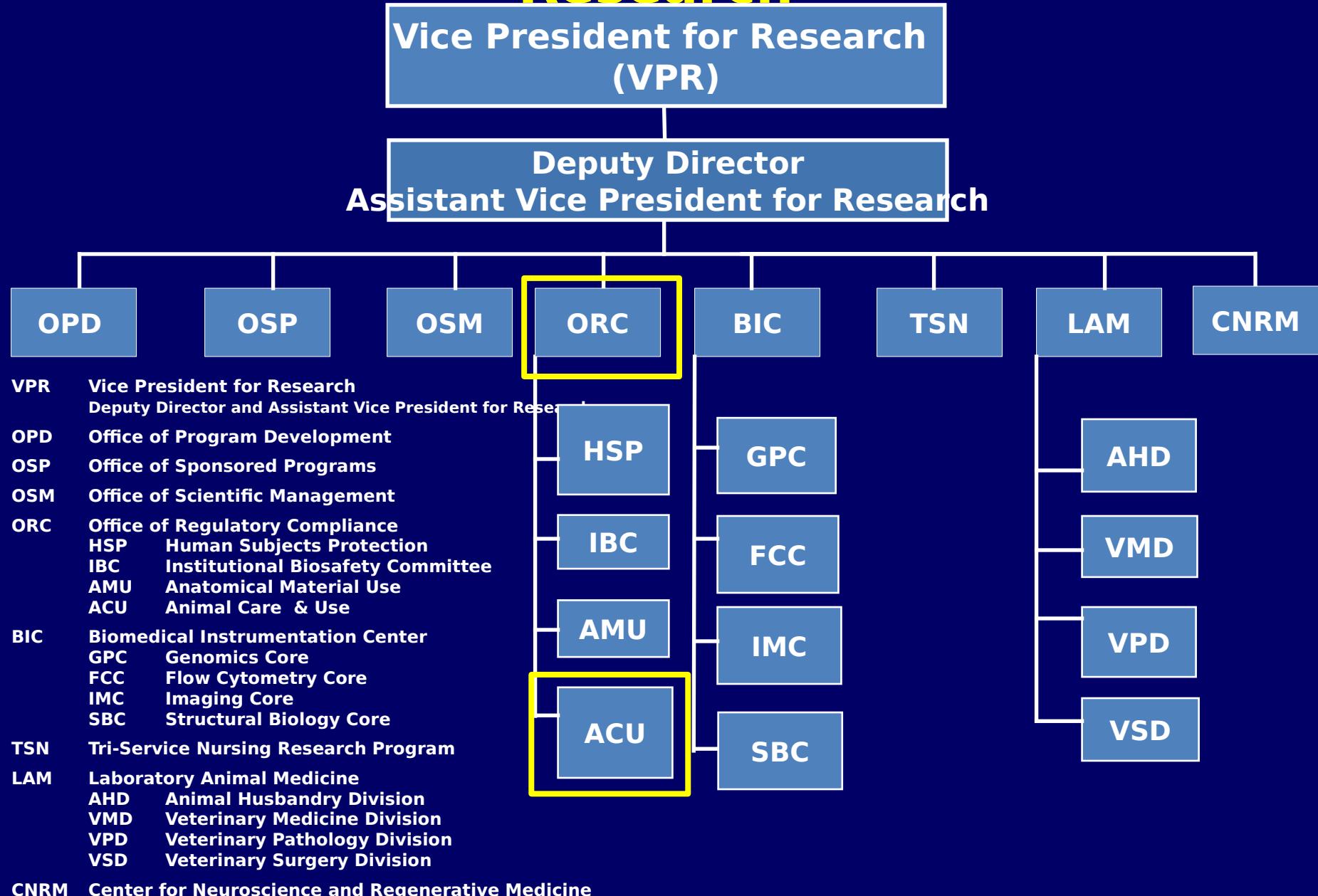
Melanie.hazzard@usuhs.mil

(301) 295-9509

AMRC

- Reviews the use of human materials in education and research conducted within the Anatomic Teaching Laboratory to ensure that it conforms to the mission of the University and to the appropriate ethical, institutional, and regulatory standards
- Meetings held at least quarterly (6/year typical)
- *<http://www.usuhs.mil/research/RegPolicies.html>*

Organizational Chart for Vice President for Research



Institutional Animal Use and Care Committee (IACUC)

IACUC Chair
Brian Cox, Ph.D.
Dept. of
Pharmacology
bcox@usuhs.mil
301-295-3223

IACUC Administrator
Ms. Megan Ralls
iacuc@usuhs.mil
301-295-3579

IACUC Coordinator
Ms. Susan Hunt
iacuc@usuhs.mil
301-295-9504

IACUC's Roles and Functions

- Reviews animal use protocols
- Reviews significant changes to protocols
- Monitors animal care and use program
- Ensures PI and University compliance with animal welfare regulations
- Inspects CAF and labs with animals 2/year
- Reviews concerns about animal care/use
- Reports out noncompliance and suspensions to OLAW and ASD(HA)

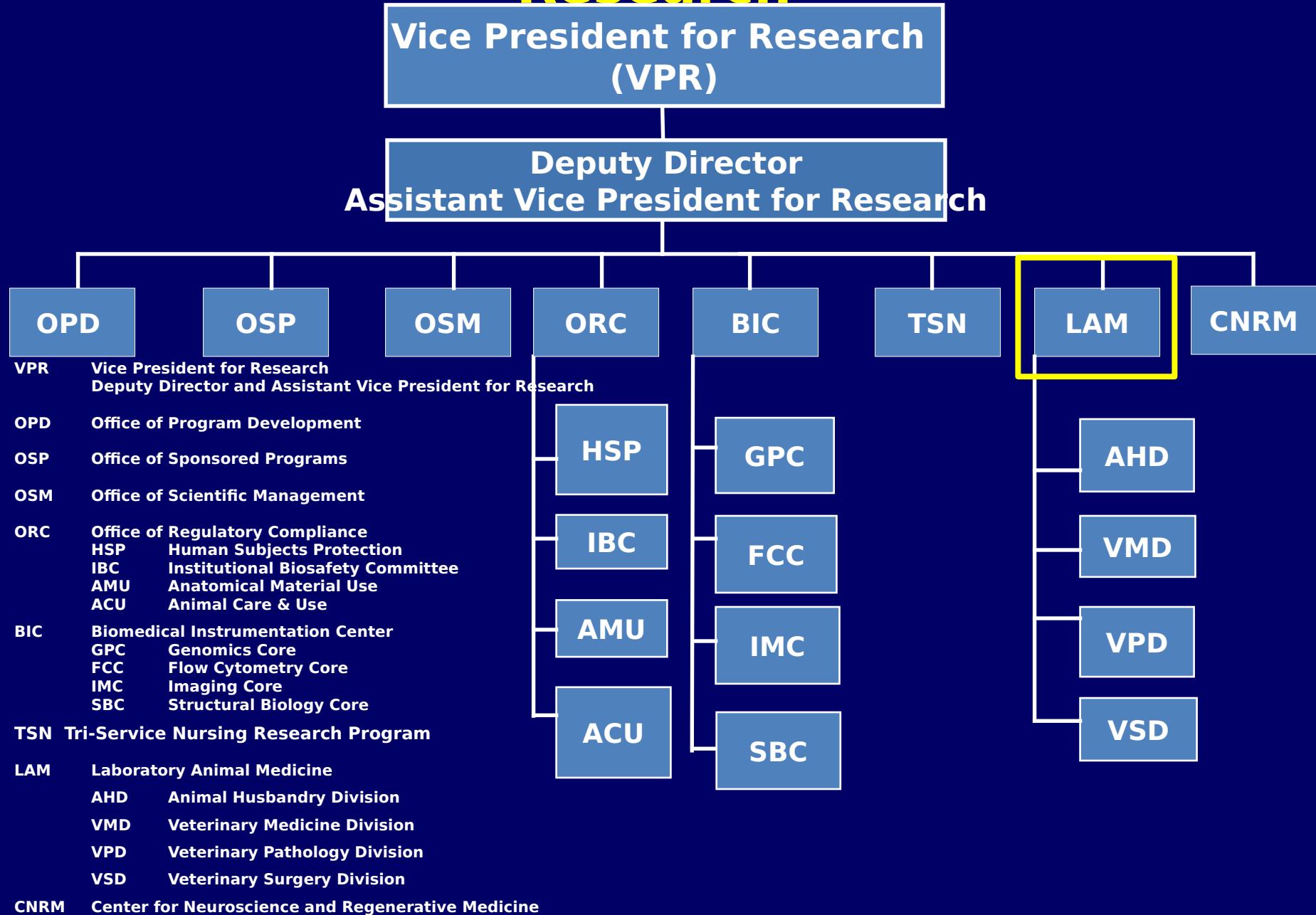
IACUC: PI's Role

- Describe use of animals in grant application(s)
- Obtain IACUC approval prior to using animals or implementing significant protocol changes
- Ensure research is conducted in accordance with the protocol
- Comply with institutional policies and procedures
- Submit amendments for any major changes, including any change in scope of work
- Address significant changes in the progress report

IACUC Facts

- Meetings held monthly (3rd Wednesday)
- Much routine business conducted electronically via email
- New protocols have mandatory vet review before IACUC review
- Protocol approval is for 3 years
- Annual review must be performed to ensure protocol compliance
- *<http://www.usuhs.mil/research/RegPolicies.html>*

Organizational Chart for Vice President for Research



Laboratory of Animal Medicine (LAM)

LTC Timothy Settle, DVM, DACVPM, DACLAM
Director

timothy.settle@usuhs.mil
301-295-3753

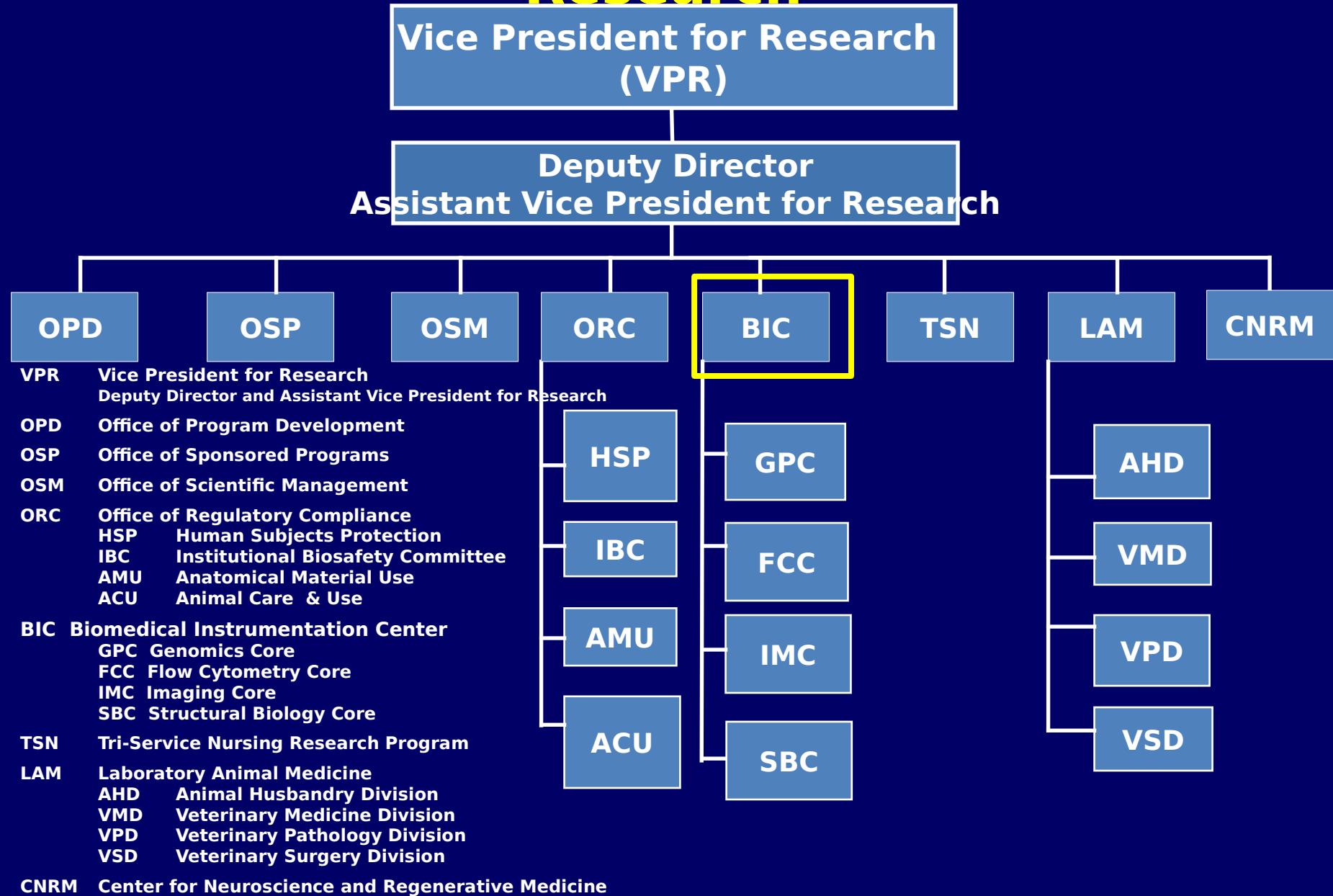
LAM

- Resources Available
 - Conventional Multispecies housing
 - Barrier housing for rodents
 - Surgery suites for research and teaching
 - Surgery & Anesthesia technical assistance
 - Fluoroscopy
 - Necropsy
 - TBI & procedure rooms

LAM

- Services Available:
 - Protocol & Animal model development
 - Protocol veterinary pre-IACUC review
 - Animal procurement
 - Animal quality assurance and quarantine
 - Animal housing and sanitation
 - Animal husbandry & health care

Organizational Chart for Vice President for Research



Biomedical Instrumentation Center (BIC)

LTC Felicia Langel, V.M.D.,
Ph.D.
Director
felicia.langel@usuhs.mil
301-295-9406

Biomedical Instrumentation Center (BIC)

- BIC is the shared instrument facility for USU.
 - Open to all members of the USU community.
- Nominal fee-for-service
 - From full service to user-independent service, depending on the instrument and the user's level of training.
- Provide expertise in protocol design.
- Provide assistance with data collection and analysis.

Biomedical Instrumentation Center (BIC)

- **Genomics**
 - DNA/RNA sequencing and synthesis
- **Microscopic Imaging**
 - Fixed and live microscopy
- **Flow Cytometry**
 - Fixed and live cell analysis and sorting
- **Histopathology**
 - Preparation of fixed and frozen tissues for microscopy
- **Structural Biology/Proteomics**
 - Molecular structure studies and protein/protein interactions
- **Translational Imaging**
 - *In vivo* and *ex vivo* MRI and PET/CT

Joint Office of Technology Transfer (JOTT)

usu
Office of
Research



**General
Counsel**

HJF

Joint Office of Technology Transfer (JOTT)

Katie Swanson-Lipka, Ph.D.

Technology Transfer Director

techtransfer@hjf.org

301-295-0450 (USU Office)

240-694-2154 (HJF HQ)

[www.hjf.org/guide/services/other/techtransfer.htm](http://www.hjf.org/guide/services/other/techtransfer.html)

Joint Office of Technology Transfer (JOTT)

Agatha Lee, Ph.D.

Technology Transfer Liaison

alee@hjf.org

301-295-0450 (USU)

240-694-2277 (HJF)

What Function does the Joint Office of Technology Transfer Serve?

To protect and commercialize novel technologies

developed by USU and HIF researchers

Research → Inventions → Patents →

Commercialization

How?

- Negotiating agreements affecting technology transfer
- Evaluating new invention disclosures
- Filing and prosecuting patent applications on novel inventions
- Marketing and licensing novel technologies
 - Including biological materials

Technology Transfer Services

- Material transfer agreements (MTA)
- Cooperative research and development agreements (CRADA)
- Nondisclosure agreements (NDA)
- Patent applications
- License agreements
- Royalty payments

Any Questions?

Henry M. Jackson Foundation

- Created in 1983 as a non-profit corporation
- Chartered by Congress to “promote the welfare of the Uniformed Services University...”
 - Supports over 200 research projects at USU
 - Over 400 employees at USU, more than 80 with Visas
 - Administers more than 100 education funds and 70 endowments
- Located 6 miles north of USU on Rockville Pike

HJF Support to USU

- Grant proposal submission assistance
- Post-award management
 - Human resources - recruiting, payroll, benefits, visas
 - Purchasing and vendor payments
 - Sub-award/sub-contract management
 - Financial management - 24/7 online reporting
 - Travel, graphics, communications services
- Education/endowment fund management
- Technology transfer

HJF Sponsored Project Administrators

- Every department has a Sponsored Project Administrator (SPA)
- Salary supported by onsite indirect cost recovery
- SPAs support investigators with proposal development and submission and post-award administration
- SPAs act as liaison between investigator, USU and HJF administration

What is a Patent?

- A Patent is a 20-year monopoly to prevent others from making, using or selling the patented invention without permission
- What is a patentable invention depends on many factors and is ultimately determined by the U.S. Patent and Trademark Office

What are the Criteria for a Patent?

- **NOVEL** - The invention must be demonstrably different from prior art (Publicly available ideas, inventions, products)
 - **USEFUL** - The invention must have some application or utility or be an improvement
 - **WRITTEN DESCRIPTION** - Sufficient detail so that a person having ordinary skill in the art can make and use the invention
 - **NON-OBVIOUS*** - The invention cannot be obvious to a person of "Ordinary Skill" in the field when viewed in light of prior art
- * This is the most frequently cited reason by patent examiners as to why an invention is not patentable

The Importance of Record Keeping

- Patents in the U.S. Are Granted to Those Who First Conceptualize an Invention and Reduce It to Practice
- Important to Document and Date
 - Conception of the Invention
 - Reduction of the Idea to Practice
- Use Bound Notebooks and Ink
 - Each Page Signed, Dated, and Witnessed

Patenting and Public Disclosures

- Public Disclosures - Publications (Papers and Abstracts), Presentations, Posters, Seminars, Internet Postings, etc.
- **U.S.** - Can apply for a patent no later than 1 year after public disclosure
- **Foreign** - Rights are lost once a public disclosure is made unless a prior patent filing has been made

Commercial value of inventions enhanced with worldwide patent protection

Inventor Participation Increases the Probability of Success

- Inventor participates in drafting initial patent application by interacting with outside patent counsel
- Inventor participates throughout patent prosecution process
 - Assists in addressing office actions from patent office
 - Adding additional data and new claims to the application
- Inventor participation during commercialization
 - Inventor assists in preparing non-confidential summaries of invention
 - Inventors are often the best source to identify licensees
 - Inventor participates in technical discussions with potential licensees
- CRADAs with licensee or potential licensee
 - Bring research money to the laboratory